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E.O. 12958: N/A
TAGS: EAGR ETRD ECON
SUBJECT: FDA REPORTABLE FOOD REGISTRY

SUBJECT:

¶1. This is an action request. Please see para 8.

¶2. On September 8, 2009, the U.S. Food and Drug Administration launched the Reportable Food Registry (RFR or the Registry), an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences to humans or animals. The Registry helps the FDA better protect public health by tracking patterns of adulteration and targeting inspections. The Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085), section 1005 directs the FDA to establish a Reportable Food Registry for Industry. The RFR applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula.

¶3. Food Facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States (Responsible Parties) should be registered under section 415(a) of the FD&C Act (21 U.S.C. 350d), Such facilities are required to report via the RFR portal (http://rfr.fda.gov) within 24 hours if they find a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Federal, state, and local government officials may voluntarily use the RFR portal to report information that may come to them about reportable foods.

¶4. The reporting requirement applies to all foods and animal feed regulated by the FDA, except infant formula and dietary supplements, which are covered by other regulatory requirements. Some examples of reasons a food may be reportable include bacterial contamination, allergen mislabeling or elevated levels of certain chemical components. More information is available at www.fda.gov/ReportableFoodRegistry .

¶5. The opening of the RFR electronic portal reflects a fundamental principle of the President's Food Safety Working Group that "preventing harm to consumers is our first priority." "President Obama has pledged to strengthen food safety," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "The opening of the Reportable Food Registry electronic portal represents a significant step toward that pledge." "By fostering real-time submission to the FDA of information on food safety hazards, the registry enhances FDA's ability to act quickly to prevent foodborne illness," said Michael ¶R. Taylor, senior advisor to the Commissioner. "Working with the food industry, we can swiftly remove contaminated products from commerce and keep them out of consumers' hands."

¶6. A Responsible Party must 1) Investigate the cause if the adulteration of food may have originated with the responsible party, 2) submit initial information,

followed by supplemental reports, and 3) work with FDA to follow up as needed. A Responsible Party is not required to report if the adulteration originated with the responsible party and it found the problem before the food was shipped and corrected the problem or destroyed the food.

¶7. In emergencies, consumers, food retailers and food service operators should continue to call FDA at 301-443-1240. For less urgent problems, contact the FDA consumer complaint coordinator in your geographic area or see Your Guide to Reporting Problems to FDA. For more information see The RFR Guidance at www.fda.gov/ReportableFoodRegistry
Consumer Inquiries: 888-INFO-FDA.

¶8. ACTION REQUEST: Posts draw from the information in points 2 through 7 to discuss this issue with the appropriate Ministries. Where FAS or HHS officials are present, Econ officers should coordinate delivery of the talking points. Please report substantive comments only via cable, at or below the SBU level. If you have questions regarding this program, please contact Vashti.Klein (vashti.klein@fda.hhs.gov) or Ann Ryan (ryanam@state.gov).
CLINTON